

**REMARKS**

Entry and consideration of the Amendment and Reply filed September 6, 2005 and of the foregoing supplemental amendments, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.114, are respectfully requested.

As indicated in the Summary of the Office Action dated May 6, 2005, claims 35-58 and 60-119 were pending in the application. Claims 35-48, 53-56, 64-75, 78-82 and 85-107 were withdrawn from consideration. By the amendment filed September 6, 2005, claims 35-48, 53-56, 64-75, 78-82 and 85-107 were canceled without prejudice or disclaimer of the subject matter described therein. Claims 49-52, 57, 58, 60-63, 76, 77, 83, 84, and 108-119 are under consideration and stand rejected.

By the present amendment, claims 49, 50, 51, 57, 58, and 61 have been amended to incorporate recitation of the stringent hybridization conditions that are described in the first full paragraph on page 5 of the Specification. Claims 120-123 have been added to recite language that was stricken or amended from claims 49-52 in the Amendment and Reply filed September 6, 2005.

No new matter is added by way of the present amendment. Any subject matter that may have been canceled by the present amendment is canceled without prejudice or disclaimer. The right to file a continuation or divisional application directed to any canceled subject matter is reserved.

**Claim rejection under 35 USC § 112:**

In the single rejection pending in the application, claims 49-52, 57, 58, 60-63, 76, 83, 84 and 108-119 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly

failing to comply with the written description requirement. The Office acknowledged that a sequence according to SEQ ID NO 1 with an open reading frame from base pair 211 to base pair 1740 is adequately described. Office Action dated May 6, 2005 at 2. However, the Office has alleged that the claims embrace products containing sequences that do not meet the written description requirements and methods of using such products. The rejection is respectfully traversed.

A person of ordinary skill in the art would clearly appreciate that the inventors were in possession of the claimed invention at the time the application was filed. All the claims, including claims 120-123 which recite language stricken from claims 49-52, satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. With respect to claims 49-52, 57, 58, 60-63, 76-77, 83-84, and 108-119, the amendments to these claims have obviated the alleged reasons for rejection so that the rejection cannot reasonably be maintained. The description of the subject matter of claims 120-123 has been presented separately so that the particular issues related thereto may be separately addressed.

***Concerning claims 49-52, 60, 62, 63, 76, 77, 83 and 84***

Claims 49-52 are directed to nucleic acid molecules and vectors encoding antisense and ribozyme molecules. The function of the encoded molecules is related to the ability of sequences contained in the molecules to bind to segment(s) of sequences encoding fucosyl transferase. The genus of sequences recited in claims 49-52, as amended, is clearly directed to molecules that will perform this function. The issue of sequences having at least 50% homology to SEQ ID NO:1 that code for a plant protein having fucosyl transferase activity was rendered moot with respect to these claims by the Amendment and Reply filed September 6, 2005, since the recitation of sequences that are at least 50% homologous was deleted from claims 49-51.

The present amendment has obviated the Examiner's remarks in the Advisory Action mailed September 23, 2005 in response to Applicants' arguments. The Examiner asserted that the Specification did not provide a specific definition of stringent hybridization conditions, but rather provided an example of stringent conditions. By the present amendment, specific stringent conditions described on page 5 of the Specification have been incorporated into the claims.

Claims 49-52, as amended, satisfy the written description requirement of 35 U.S.C. § 112, first paragraph for reasons that are clearly explained by the training materials published by the Office to show how the Written Description guidelines are to be applied in examining claims. *See, e.g., Revised Interim Written Description Guidelines Training Materials* at Example 9, (<http://www.uspto.gov/web/offices/pac/writtendesc.pdf>)

(“Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.”);

*see also, Synopsis of the Application of the Written Description Guidelines* at Example 9 (<http://www.uspto.gov/web/menu/written.pdf>).

The requirement of stringent hybridization to SEQ ID NO:1 under the conditions defined in the claims provides a sufficient description of the sequences recited in the present claims. A person of ordinary skill in the art would not expect substantial variation among species encompassed within the scope of this recitation. Accordingly, a person skilled in the art would be able to recognize sequences within the genus and would have appreciated that the inventors were in possession of the recited genus.

Furthermore, it must be noted that claims 49-50 are directed to a vector for expressing antisense DNA. Claim 51 is directed to a DNA molecule encoding a ribozyme, and claim 52 is directed to a vector comprising the molecule of claim 51. As such, one skilled in the art would recognize that it is not necessary that the sequence(s), or partial sequence(s), contained in these constructs actually encode a protein having fucosyl transferase activity. Rather, the antisense sequence need only hybridize with the target sequence. Therefore, a person of skill in the art would recognize that the recited hybridization conditions are directly related to the functional aspects of the structure of the claimed vectors and DNA molecules.

Claims 60, 62, 63, 76, 77, 83 and 84 depend from claim 51 and no grounds of rejection separate from the allegations directed at claims 49-52 have been alleged. Therefore, the subject matter of these claims is also adequately described.

For at least the foregoing reasons, withdrawal of the rejection of claims 49-52, 60, 62, 63, 76, 77, 83 and 84 is specifically requested.

***Concerning claims 57, 58, 61, 63 and 108-119***

Claims 57-58 and 61 are directed to methods of preparing recombinant hosts comprising a vector expressing an antisense molecule or of preparing a recombinant host comprising a homologous recombination. The adequacy of the written description supporting these claims is provided by the description of the steps that comprise the methods.

While claims 49-52 are directed to molecules comprising certain structural features, claims 57-58 and 61 are directed to methods that comprise steps. It logically follows that where the question of the sufficiency of the written description for a chemical compound is whether the structural elements of the molecule are sufficiently described, the question with respect to a method must be whether the steps of the method are sufficiently described. The

two sets of claims are related in that claims 49-52 describe molecules that may be used in the method of claims 57, 58 and 61, and the claims that depend from these claims

In the Advisory Action Dated September 23, 2005, the Examiner asserted that Applicants have not explained why the previous rejection does not apply to amended claims 57, 58 and 61. The alleged basis for the rejection is that "The construction of the antisense and ribozyme vectors for use in the claimed [methods] require a description of the specific plant alpha-1,3-fucosyl transferase sequences targeted." Office Action dated May 6, 2005 at 6. To be applied to method claims 57, 58, and 61 and the claims depending thereon, this allegation must be read to allege that the step of inserting the recited sequences into the host was not adequately described because the sequences were allegedly not adequately identified, which is to imply that a necessary step was allegedly missing.

While Applicants disagree with the foregoing allegation for the reasons previously stated, the rejection clearly can not be reasonably applied to the claims as amended, because claims 57-58 and 61 were amended to recite a step of identifying a DNA sequence in a host that codes for a protein having fucosyl transferase activity. In the recited step this is done by using SEQ ID NO:1 as a reference such that the identified sequence corresponds to a part of SEQ ID NO:1 or bears sufficient similarity so that it is more than 50% homologous or hybridizes under stringent conditions to SEQ ID NO:1.

The amendment to the claims makes it clear that identification of a sequence to use in a given host is a step in the method. Whether or not the sequence is known *a priori*, the sequence can be determined, for example, as described in the specification and/or by any other method a skilled practitioner may employ with reference to the teachings of the specification. Following the identification step, a sequence derived from the identified sequence can be used to perform the remainder of the method as described.

The Specification describes how to identify the sequences and exemplifies the identification step, and in the process identifies a representative sequence. The identification step is fully described and can be performed on any of the recited hosts. At pages 18-19, the specification describes how to identify fucosyl transferase coding sequences in hosts using sequences from SEQ ID NO:1. At page 6, the specification teaches that the conserved sequence of SEQ ID NO:3 is particularly useful for sequence recognition. Of course, the identification of a sequence need not comprise a screening step. Sequences may also be identified from the knowledge of the skilled practitioner by sequence comparison methods using SEQ ID NO:1, for example, in mung bean, or where genome sequencing data is available or by reference to experience whenever the method is repeated on a host of a given type. The Office has not questioned the written description of any other aspect of the recited methods. Therefore, all the steps of the methods of claims 57, 58, 61, 63 and 108-119 are described.

The question with respect to claims 57, 58, 61, 63 and 108-119 is not whether the material identified by carrying out a step in the method is described *a priori*, but whether the individual method steps of claims 57, 58 and 61 are described. The steps of the presently claimed methods are fully described so that a person of ordinary skill would recognize that the claimed method can be practiced on any of the recited hosts, and the inventors were in possession of the method as claimed at the time the application was filed.

For at least the foregoing reasons, withdrawal of the rejection of claims 57, 58, 61, 63 and 108-119 is specifically requested.

*Concerning new claims 120-123*

Claims 120-123 have been added to recite language that was stricken from claims 49-52 in the Amendment and Reply so that the allegations of the Office with respect to this language could be separately addressed. The recited genus of sequences which are at least 50% homologous with the sequence according to SEQ ID NO 1 comprises a mathematically defined set of sequences that could be instantly recognized by computer sequence comparison. Among this set of sequences, one skilled in the art would be able to predict which of such sequences would code for a protein having fucosyl transferase activity by reference to SEQ ID NO 1 as a representative species. For example, sequences having silent mutations, having mutations encoding conservative amino acid substitutions, and mutations that do not substantially disturb the conserved sequence according to SEQ ID NO: 3, which is described beginning at page 6 of the specification would be expected to have fucosyl transferase activity.

Furthermore, the recited degree of homology is consistent with the levels of homology seen among functionally identical fucosyl transferase enzymes. For example sequences encoding fucosyl transferase enzymes from mosses have nucleic acid identities of about 50-60% and are functionally the same at the enzyme level.

Therefore, SEQ ID NO:1 is in fact a representative of the recited genus and a person of ordinary skill in the art would recognize that the inventors were in fact in possession of the claimed invention at the time the application was filed.

**CONCLUSION**

For at least the foregoing reasons, all the claims as currently presented meet the written description requirement of 35 U.S.C. § 112, first paragraph. Withdrawal of the single remaining rejection is respectfully requested.

Further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

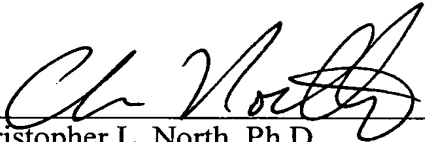
The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL PC

Date: January 12, 2006

By: \_\_\_\_\_

  
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